FORM PTO-1390 (REV 5-93) U S DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		ATTORNEY'S DOCKET NUMBER
TRANSMITTAL LETTER TO THE UNITED STATES DESIGNATED/ELECTED OFFICE (DO/EO/US) CONCERNING A FILING UNDER 35 U.S.C. 371		1960.237
		U S APPLICATION NO (If known, see 37 C F R 1 5) 60/094,950 09/744950
INTERNATIONAL APPLICATION NO	INTERNATIONAL FILING DATE	PRIORITY DATE CLAIMED
PCT/CA99/00695	29 July 1999 (20.07.99)	31 July 1998 (31.07.98)

TITLE OF INVENTION

BIFURCATED STENT DELIVERY SYSTEM AND METHOD OF USE

APPLICANT(S) FOR DO/EO/US

NOVO RPS ULC

Applicant herewith submits to the United States Designated/Elected Office (DO/EO/US) the following items and other information:

1. [X] This is a **FIRST** submission of items concerning a filing under 35 U.S.C. 371.
2. [ ] This is a **SECOND** or **SUBSEQUENT** submission of items concerning a filing under 35 U.S.C. 371.
3. [X] This express request to begin national examination procedures (35 U.S.C. 371(f)) at any time rather than delay examination until the expiration of the application time limit set in 35 U.S.C. 371(b) and PCT Articles 22 and 39(1).
4. [X] A proper Demand for International Preliminary Examination was made by the 19th month from the earliest claimed priority date.
5. [X] A copy of the International Application as filed (35 U.S.C. 371(c)(2))
   a. [X] is transmitted herewith (required only if not transmitted by the International Bureau).
   b. [ ] has been transmitted by the International Bureau.
   c. [ ] is not required, as the application was filed in the United States Receiving Office (RO/US).
6. [ ] A translation of the International Application into English (35 U.S.C. 371(c)(2)).
7. [ ] Amendments to the claims of the International Application under PCT Article 19 (35 U.S.C. 371(c)(3))
   a. [ ] are transmitted herewith (required only if not transmitted by the International Bureau).
   b. [X] have been transmitted by the International Bureau.
   c. [ ] have not been made; however, the time limit for making such amendments has NOT expired.
   d. [ ] have not been made and will not be made.
8. [ ] A translation of the amendments to the claims under PCT Article 19 (35 U.S.C. 371(c)(3)).
9. [ ] An oath or declaration of the inventor(s) (35 U.S.C. 371(c)(4)).
10. [ ] A translation of the annexes to the International Preliminary Examination Report under PCT Article 36 (35 U.S.C. 371(c)(5)).

Items 11. to 16. below concern other document(s) or information included:

11. [X] An Information Disclosure Statement under 37 CFR 1.97 and 1.98.
12. [ ] An assignment document for recording. A separate cover sheet in compliance with 37 CFR 3.28 and 3.31 is included.
13. [X] A FIRST preliminary amendment.
    [ ] A SECOND or SUBSEQUENT preliminary amendment.
14. [ ] A substitute specification.
15. [ ] A change of power of attorney and/or address letter.
16. [X] Other items or information: Notif. of Transmittal of the Internat'l Search Report Or Declaration; Internat'l Prelim.Exam.

U.S. APPLICATION NO. (If known, see 37 C.F.R 1.5)	INTERNATIONAL APPLICATION NO	ATTORNEY'S DOCKET NUMBER
60/094,950 09/744950	PCT/CA99/00695	1960.237

17. [X] The following fees are submitted:

	CALCULATIONS	PTO USE ONLY
Basic National Fee (37 CFR 1.492(a)(1)-(5):		
Search Report has been prepared by the EP or JPO **$860.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.492(a)(1)) **$690.00**		
No international preliminary examination fee paid to USPTO (37 CFR 1.492 (a)(1)) but international search fee paid to USPTO (37 CFR 1.492(a)(2)) **$710.00**		
Neither international preliminary examination fee (37 CFR 1.492(a)(1)) nor international search fee (37 CFR 1.492(a)(2)) paid to USPTO **$1,000.00**		
International preliminary examination fee paid to USPTO (37 CFR 1.492 (a)(4)) and all claims satisfied provisions of PCT Article 33(1)-(4) **$100.00**		
ENTER APPROPRIATE BASIC FEE AMOUNT =	$1,000.00	
Surcharge of **$130.00** for furnishing the oath or declaration later than [ ]20 [ ]30 months from the earliest claimed priority date (37 CFR 1.492(e)).	$	

Claims	Number Filed	Number Extra	Rate	
Total Claims	60 -20 =	40	X **$18.00**	$720.00
Independent Claims	3 - 3 =	0	X **$80.00**	$000.00
Multiple dependent claim(s) (if applicable)			+ **$270.00**	$000.00
		TOTAL OF ABOVE CALCULATIONS =		$1,720.00
Reduction by 1/2 for filing by small entity, if applicable. Verified Small Entity statement must also be filed. (Note 37 CFR 1.9, 1.27, 1.28).				$
		SUBTOTAL =		$1,720.00
Processing fee of **$130.00** for furnishing the English translation later than [ ]20 [ ]30 months from the earliest claimed priority date (37 CFR 1.492(f)).				$
		TOTAL NATIONAL FEE =		$1,720.00
Fee for recording the enclosed assignment (37 CFR 1.21(h)). The assignment must be accompanied by an appropriate cover sheet (37 CFR 3.28, 3.31). **$40.00** per property +				$
		TOTAL FEES ENCLOSED =		$1,720.00
			Amount to be:	
			refunded	$
			charged	$

a. A check in the amount of $_____ to cover the above fees is enclosed.

b. Please charge my Deposit Account No. 50-1710 in the amount of $ 1,720.00 to cover the above fees. A duplicate copy of this sheet is enclosed.

c. [X] The Commissioner is hereby authorized to charge any additional fees which may be required, or credit any overpayment to Deposit Account No. 50-1710 . A duplicate copy of this sheet is enclosed.

NOTE: Where an appropriate time limit under 37 CFR 1.494 or 1.495 has not been met, a petition to revive (37 CFR 1.137(a) or (b)) must be filed and granted to restore the application to pending status.

SEND ALL CORRESPONDENCE TO: Katten Muchin Zavis
Patent Administrator

525 West Monroe Street, Suite 1600

Chicago, Illinois 60661-3693

Facsimile: (312) 902-1061

SIGNATURE

RICHARD P. BAUER — January 31, 2001
NAME — DATE

31,588
REGISTRATION NUMBER

1960.237

PATENT APPLICATION

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:	)	
	:	Examiner: NYA
DONALD R. RICCI, ET AL.	)	
	:	Group Art Unit: NYA
Application No.: NYA	)	
	:	
Filed: January 31, 2001	)	
	:	
For: BIFURCATED STENT DELIVERY SYSTEM AND METHOD OF USE	) :)	January 31, 2001

Commissioner for Patents
Washington, D.C. 20231

PRELIMINARY AMENDMENT

Sir:

Prior to examination on the merits, kindly amend the above-identified application as follows:

IN THE CLAIMS:

Kindly cancel Claims 1-55 without prejudice.

Kindly add Claims 56-115 as follows:

--56. An endovascular sleeve for delivering a pair of guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal

end extending beyond the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway;

characterized in that a guidewire is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire.

57. The endovascular sleeve defined in claim 56, further comprising a radioopaque marker disposed thereon.

58. The endovascular sleeve defined in claim 57, wherein the radioopaque marker is disposed at the junction.

59. The endovascular sleeve defined in claim 56, wherein the first passageway has a substantially circular cross-section.

60. The endovascular sleeve defined in claim 56, wherein the second passageway has a substantially circular cross-section.

61. The endovascular sleeve defined in claim 56, wherein both the first passageway and the second passageway have a substantially circular cross-section.

62. The endovascular sleeve defined in claim 56, wherein the first distal end extends beyond the second distal end by a margin of at least about 0.3 cm.

63. The endovascular sleeve defined in claim 56, wherein the first distal end extends beyond the second distal end by a margin in the range of from about 0.3 to about 3 cm.

64. The endovascular sleeve defined in claim 56, wherein the first distal end extends beyond the second distal end by a margin in the range of from about 0.5 to about 2 cm.

65. The endovascular sleeve defined in claim 56, wherein the first distal end is chamfered.

66. The endovascular sleeve defined in claim 56, wherein the second distal end is chamfered.

67. The endovascular sleeve defined in claim 56, wherein both the first distal end and the second distal end are chamfered.

68. A bifurcated stent delivery system for delivery of an expansible prosthesis to a bifurcated body passageway, the system comprising:

a catheter;

guidewire; and

an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end extending beyond than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway;

characterized in that the guidance is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire.

69. The kit defined in claim 68, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

70. The kit defined in claim 69, wherein the radioopaque marker is disposed at the junction.

71. The kit defined in claim 68, wherein the first passageway has a substantially circular cross-section.

72. The kit defined in claim 68, wherein the second passageway has a substantially circular cross-section.

73. The kit defined in claim 68, wherein both the first passageway and the second passageway have a substantially circular cross-section.

74. The kit defined in claim 68, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

75. The kit defined in claim 68, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

76. The kit defined in claim 68, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

77. The kit defined in claim 68, wherein the first distal end is chamfered.

78. The kit defined in claim 68, wherein the second distal end is chamfered.

79. The kit defined in claim 68, wherein both the first distal end and the second distal end are chamfered.

80. The kit defined in claim 68, wherein the catheter comprises at least one expandable member.

81. The kit defined in claim 80, wherein the expandable member is disposed adjacent a distal end of the catheter.

82. The kit defined in claim 80, wherein the catheter comprises two expandable members.

83. The kit defined in claim 80, wherein the catheter comprises a substantially Y-shaped expandable member.

84. The kit defined in claim 80, wherein the expandable member is a balloon.

85. The kit defined in claim 80, further comprising a bifurcated stent disposed on the expandable member.

86. The kit defined in claim 85, wherein the bifurcated stent is mounted on the expandable member.

87. A method for delivery of a bifurcated stent to a target bifurcated body passageway having a proximal body passageway, a first distal body passageway and a second distal body passageway using an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first

tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway, the method comprising the steps of:

(i)navigating a first guidewire through the primary proximal body passageway and into the first distal body passageway;

(ii) feeding the first tubular passageway of the endovascular sleeve over the first guidewire;

(iii) navigating the endovascular sleeve through the primary proximal body passageway until the first distal end is disposed in the first distal body passageway and the junction abuts a crotch in the bifurcated body passageway;

(iv) navigating a second guidewire through the second tubular passageway and into the second distal body passageway;

(v) withdrawing the endovascular sleeve from the body passageway;

(vi) guiding a catheter over the first guidewire and the second guidewire, the catheter having a bifurcated stent disposed thereon;

(vii) navigating the bifurcated stent to the target bifurcated body passageway; and

(viii) expanding the bifurcated stent.

88. The method defined in claim 87, wherein the catheter further comprises at least one expandable member on which the bifurcated stent is disposed and Step (viii) comprises expanding the expandable member to convey a radially expansive force to the bifurcated stent.

89. The method defined in claim 88, wherein the expandable member is disposed adjacent a distal end of the catheter.

90. The method defined in claim 88, wherein the catheter comprises two expandable members.

91. The method defined in claim 88, wherein the catheter comprises a substantially Y-shaped expandable member.

92. The method defined in claim 88, wherein the expandable member is a balloon.

93. The method defined in claim 87, wherein the bifurcated stent is constructed of a plastically deformable material.

94. The method defined in claim 87, wherein the bifurcated stent is constructed of stainless steel.

95. The method defined in claim 87, wherein the bifurcated stent is constructed of a self-expanding material.

96. The method defined in claim 87, wherein the catheter further comprises a sheath covering the bifurcated stent and Step (viii) comprises removing the sheath to expose the bifurcated stent resulting in a radially expansive force thereon.

97. The method defined in claim 95, wherein the self-expanding material is nitinol.

98. The method defined in claim 95, wherein the self-expanding material expands at a temperature of greater than about 30°C.

99. The method defined in claim 95, wherein the self-expanding material expands at a temperature of in the range of from about 30° to about 40°C.

100. The method defined in claim 87, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

101. The method defined in claim 100, wherein the radioopaque marker is disposed at the junction.

102. The method defined in claim 87, wherein the first passageway has a substantially circular cross-section.

103. The method defined in claim 87, wherein the second passageway has a substantially circular cross-section.

104. The method defined in claim 87, wherein both the first passageway and the second passageway have a substantially circular cross-section.

105. The method defined in claim 87, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

106. The method defined in claim 87, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

107. The method defined in claim 87, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

108. The method defined in claim 87, wherein the first distal end is chamfered.

109. The method defined in claim 87, wherein the second distal end is chamfered.

110. The method defined in claim 87, wherein both the first distal end and the second distal end are chamfered.

111. The endovascular sleeve defined in claim 56, wherein the second proximal end extends beyond the first proximal end.

112. The endovascular sleeve defined in claim 111, wherein the first tubular passageway has a length such that the first proximal end does not emanate from a subject and the second tubular passageway has a length such that the second proximal emanates from the subject.

113. The endovascular sleeve defined in claim 56, wherein the second proximal end the first proximal end and the second proximal end are substantially juxtaposed.

114. The endovascular sleeve defined in claim 113, wherein the first tubular passageway and the second tubular passageway have a length such that the first proximal end and the second proximal end each emanate from a subject.

115. The endovascular sleeve defined in claim 56, wherein the first tubular passageway and the second tubular passageway are each constructed of a material having sufficient integrity to be navigated through tortuous body passageways.--

Applicants' undersigned attorney may be reached in our Washington, D.C. office by telephone at (202) 625-3500. All correspondence should continue to be directed to our address given below.

Respectfully submitted,

Attorney for Applicants

Registration No. 31,588

PATENT ADMINISTRATOR
KATTEN MUCHIN ZAVIS
525 West Monroe Street
Suite 1600
Chicago, Illinois 60661-3693
Facsimile: (312) 902-1061

PCT/CA 31 JAN 2001
09/744950
PCT/CA99/00695

BIFURCATED STENT DELIVERY SYSTEM AND METHOD OF USE

TECHNICAL FIELD

In one of its aspects, the present invention relates to an endovascular sleeve for use in delivery of a bifurcated stent. In another of its aspects, the present invention relates to bifurcated stent delivery kit. In yet another of its aspects, the present invention relates to a method for delivery of a bifurcated stent.

BACKGROUND ART

Stents are generally known. Indeed, the term "stent" has been used interchangeably with terms such as "intraluminal vascular graft" and "expansible prosthesis". As used throughout this specification, the term "stent" is intended to have a broad meaning and encompasses any expandable prosthetic device for implantation in a body passageway (e.g., a lumen or artery).

In the past ten years, the use of stents has attracted an increasing amount of attention due the potential of these devices to be used, in certain cases, as an alternative to surgery. Generally, a stent is used to obtain and maintain the patency of the body passageway while maintaining the integrity of the passageway. As used in this specification, the term "body passageway" is intended to have a broad meaning and encompasses any duct (e.g., natural or iatrogenic) within the human body and can include a member selected from the group comprising: blood vessels, respiratory ducts, gastrointestinal ducts and the like.

Stent development has evolved to the point where the vast majority of currently available stents rely on controlled plastic deformation of the entire structure of the stent at the target body passageway so that only sufficient force to maintain the patency of the body passageway is applied during expansion of the stent.

Generally, in many of these systems, a stent, in association with a balloon, is delivered to the target area of the body passageway by a catheter system. Once the stent has been properly located (for example, for intravascular implantation

the target area of the vessel can be filled with a contrast medium to facilitate visualization during fluoroscopy), the balloon is expanded thereby plastically deforming the entire structure of the stent so that the latter is urged in place against the body passageway. As indicated above, the amount of force applied is at least that necessary to expand the stent (i.e., the applied the force exceeds the minimum force above which the stent material will undergo plastic deformation) while maintaining the patency of the body passageway. At this point, the balloon is deflated and withdrawn within the catheter, and is subsequently removed. Ideally, the stent will remain in place and maintain the target area of the body passageway substantially free of blockage (or narrowing).

See, for example, any of the following patents:

United States patent 4,733,665 (Palmaz),
United States patent 4,739,762 (Palmaz),
United States patent 4,800,882 (Gianturco),
United States patent 4,907,336 (Gianturco),
United States patent 5,035,706 (Gianturco et al.),
United States patent 5,037,392 (Hillstead),
United States patent 5,041,126 (Gianturco),
United States patent 5,102,417 (Palmaz),
United States patent 5,147,385 (Beck et al.),
United States patent 5,282,824 (Gianturco),
United States patent 5,316,023 (Palmaz et al.),
Canadian patent 1,239,755 (Wallsten),
Canadian patent 1,245,527 (Gianturco et al.),
Canadian patent application number 2,171,047 (Penn et al.),
Canadian patent application number 2,175,722 (Penn et al.),
Canadian patent application number 2,185,740 (Penn et al.),
Canadian patent application number 2,192,520 (Penn et al.),
International patent application PCT/CA97/00151 (Penn et al.), and
International patent application PCT/CA97/00152 (Penn et al.),

the contents of each of which are hereby incorporated by reference, for a discussion on previous stent designs and deployment systems.

All of the stents described in the above-identified patents share the common design of being mono-tubular and thus, are best suited to be delivered and implanted in-line in the body passageway. These known stents are inappropriate for use in a bifurcated body passageway (e.g., a body passageway comprising a parent passageway that splits into a pair of passageways). Further, these stents are inappropriate for use in a body passageway having side branches since: (i) inaccurate placement of the stent substantially increases the risk to the patient, (ii) the risk of passageway closure in the side branches is increased, and (iii) the side branches will be substantially inaccessible.

Indeed, the Physician Guide published in support of the Palmaz-Schatz stent states on page 32 (the contents of which are hereby incorporated by reference):

> " ... no attempt should be made following placement of a PALMAZ-SCHATZ stent to access the side branch with a guide wire or a balloon, as such attempts may result in additional damage to the target vessel or the stent. Attempts to treat obstructed side branches within stented segments can result in balloon entrapment, necessitating emergency bypass surgery."

Thus, when installed, the Palmaz-Schatz stent admittedly shields side branches emanating from the target area of the body passageway effectively permanently. This can be problematic since the only way to treat blockage or other problems associated with the side branches is to perform the type of surgery which installation of the stent was intended to avoid.

This contraindication for conventional mono-tubular stents is corroborated by a number of investigators. See, for example, the following:

1. *Interventional Cardiovascular Medicine: Principles and Practice* (1994); Publisher: Churchill Livingstone Inc.;

pages 221-223 (Ohman et al.), 487-488 (Labinaz et al.), 667-668 (Bashore et al.) and 897 (Bailey et al.), including references cited therein;

2. Gianturco-Roubin Flex-Stent™ Coronary Stent: Physician's Guide; page 2, Paragraph 3 under WARNINGS;

3. *Circulation*, Vol. 83, No. 1, January 1991 (Schatz et al.); entitled "Clinical Experience With the Palmaz-Schatz Coronary Stent"; pages 148-161 at page 149; and

4. *American Heart Journal*, Vol. 127, No. 2, February 1994 (Eeckhout et al.); entitled "Complications and follow-up after intracoronary stenting: Critical analysis of a 6-year single-center experience"; pages 262-272 at page 263,

the contents of each of which are hereby incorporated by reference.

Further, some investigators have attempted to install individual stents in each branch of the bifurcated body passageway. However, this approach is fraught with at least two significant problems. First, implantation of three individual stents is technically challenging and, together with the expansive forces generated upon implantation, results in subjecting the central walls of the bifurcated body passageway to undue stress and trauma which may lead to post-procedural complications. Second, since the central walls (i.e., in the crotch area) of the bifurcated body passageway are not supported by the individual stents, this area of the passageway is left substantially unprotected and susceptible to blockage.

One particular problem area with bifurcated body passageways is the occurrence of bifurcation lesions within the coronary circulation. Generally, these legions may be classified as follows:

Type	Characteristic
A	Prebranch stenosis not involving the ostium of the side branch;
B	Postbranch stenosis of the parent vessel not involving the origin of the side branch;
C	Stenosis encompassing the side branch but not involving the ostium;
D	Stenosis involving the parent vessel and ostium of the side branch;
E	Stenosis involving the ostium of the side branch only; and
F	Stenosis discretely involving the parent vessel and ostium of the side branch.

See *Atlas of Interventional Cardiology* (Popma et al.), 1994, pages 77-79, the contents of which are hereby incorporated by reference. The presence of bifurcation lesions is predictive of increased procedural complications including acute vessel closure.

United States patent 4,994,071 (MacGregor), the contents of which are hereby incorporated by reference, discloses a bifurcating stent apparatus. The particular design incorporates a series of generally parallel oriented loops interconnected by a sequence of "half-birch" connections. The lattice structure of the illustrated stent is constructed of wire. The use of such wire is important to obtain the loop structure of the illustrated design. United States patents 3,993,078 (Bergentz et al.) and 5,342,387 (Summers), the contents of each of

which are hereby incorporated by reference, also disclose and illustrate a bifurcated stent design constructed of wire.

In published Canadian patent application number 2,134,997 (Penn et al.) and published International patent application PCT/CA97/00294 (Penn et al.), the contents of each of which are hereby incorporated by reference, we describe various novel bifurcated stents.

Thus, while bifurcated stents are generally known, the base of knowledge relating thereto is significantly less than that relating to monotubular stents. Not surprisingly there is a similar imbalance of knowledge relating to the delivery systems for such stents. Specifically, there is vast knowledge relating delivery systems for monotubular stents compared to the knowledge that exists for bifurcated stent delivery systems.

In the delivery of any stent (monotubular or bifurcated) it is reasonably well accepted that the stent is mounted on a catheter which is navigated over a guidewire previously inserted through a guide catheter to the target location. Thus, when the object is to deliver a bifurcated stent, it is envisaged that a pair of guidewires would be used - i.e., one for each of the two passageways that branch off the primary passageway. As such, it is important that, in the primary passage, the guidewires do not become entangled, either in the guide catheter or the body passageway, as this will prevent navigation of the catheter to the target location. In addition, the limited size of the guide catheter determines the bulkiness of the bifurcated stent delivery system. The practical result of this is that the current approach of delivering bifurcated stents is bulky, cumbersome and technically challenging. To date, the present inventors are unaware of a solution to the problems of conventional bifurcated stent delivery.

Accordingly, it would be desirable to have a system which could be used to navigate a pair of guidewires in a substantially untangled manner to facilitate delivery of the bifurcated stent. It would be further advantageous is such a system were relatively miniaturized compared to conventional bifurcated stent delivery systems.

DISCLOSURE OF THE INVENTION

It is an object of the present invention to provide a novel bifurcated stent delivery system which obviates or mitigates at least one of the above-mentioned disadvantages of the prior art.

Thus, in one of its aspects, the present invention provides an endovascular sleeve for delivering a pair of guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

A bifurcated stent delivery kit for delivery of a bifurcated stent to a bifurcated body passageway, the kit comprising:

a catheter;

a pair of guidewires; and

an endovascular sleeve for delivering the guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway.

In yet another of its aspects, the present invention provides method for delivery of a bifurcated stent to a target bifurcated body passageway having a proximal body passageway, a first distal body passageway and a second distal body passageway using an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define

a junction which abuts against a crotch in the bifurcated body passageway, the method comprising the steps of:

(i) navigating a first guidewire through the primary proximal body passageway and into the first distal body passageway;

(ii) feeding the first tubular passageway of the endovascular sleeve over the first guidewire;

(iii) navigating the endovascular sleeve through the primary proximal body passageway until the first distal end is disposed in the first distal body passageway and the junction abuts a crotch in the bifurcated body passageway;

(iv) navigating a second guidewire through the second tubular passageway and into the second distal body passageway;

(v) withdrawing the endovascular sleeve from the body passageway;

(vi) guiding a catheter over the first guidewire and the second guidewire, the catheter having a bifurcated stent disposed thereon;

(vii) navigating the bifurcated stent to the target bifurcated body passageway; and

(viii) expanding the bifurcated stent.

Thus, the present inventors have developed an endovascular sleeve which can be utilized to navigate a pair of guidewires to a bifurcated body passageway such that, once in place, the guidewires are substantially untwisted or untangle. This greatly facilitates delivery of the bifurcated stent to the bifurcated artery.

BRIEF DESCRIPTION OF THE DRAWINGS

Embodiments of the present invention will be described with reference to the accompanying drawings wherein like numerals designate like parts and in which:

Figure 1 illustrates a side elevation of a first embodiment of the present endovascular sleeve;

Figure 2 illustrates a side elevation of a second embodiment of the present endovascular sleeve;

Figures 3-7 illustrate enlarged views of how the present endovascular sleeve may be used to deliver a pair of guidewires;

Figures 8-12 illustrate perspective views of how the present endovascular sleeve may be used to deliver a pair of guidewires;

Figures 13-15 illustrate enlarged view of how a bifurcated stent may be delivered once the pair of guidewires are in place; and

Figure 16 illustrates an enlarged view of the implanted bifurcated stent delivered in Figures 13-15.

BEST MODE FOR CARRYING OUT THE INVENTION

With reference to Figure 1, there is shown an endovascular sleeve 10. Endovascular sleeve 10 comprises a first tubular passageway 20 having a first distal end 22 and first proximal end 24. Endovascular sleeve 10 further comprises a second tubular passageway 30 having a second distal end 32 and second proximal end 34. First tubular passageway 20 and second tubular passageway 30 are joined and fixed with respect to one another along a seam 40. As illustrated, first distal end 22 extends beyond second distal end 32. This offset between first distal end 22 and second distal end 32 defines a junction 45 Preferably, first distal end 22 extends beyond second distal end 32 by a margin of at least about 0.3 cm, more preferably by a margin in the range of from about 0.3 cm to about 3 cm, most preferably by a margin in the range of from about 0.5 cm to about 2 cm. Further, first proximal end 24 is significantly offset with respect to second proximal end 34. As will be developed below, this offset renders endovascular sleeve 10 as a "over-the-wire/monorail" delivery system. As shown, each of first distal end 22 and second distal end 32 are chamfered or bevelled.

With reference to Figure 2, there is shown an endovascular sleeve 100. Endovascular sleeve 100 comprises a first tubular passageway 120 having a first distal end 122 and first proximal end 124. Endovascular sleeve 100 further comprises a second tubular passageway 130 having a second distal end 132 and second proximal end 134. First tubular passageway 120 and second tubular passageway 130 are joined and fixed with respect to one another along a seam 140. As illustrated, first distal end 122 extends beyond second distal end 132. This offset between first distal end 122 and second distal end 132 defines a

junction 145. Preferably, first distal end 122 extends beyond second distal end 132 by a margin of at least about 0.3 cm, more preferably by a margin in the range of from about 0.3 cm to about 3 cm, most preferably by a margin in the range of from about 0.5 cm to about 2 cm. Further, unlike in the "over-the-wire/monorail" delivery system illustrated in Figure 1, first proximal end 124 is substantially even with respect to second proximal end 134. This relatively even disposition of first proximal end 124 and second proximal end 134 renders endovascular sleeve 100 as a "double over-the-wire" delivery system. As shown, each of first distal end 122 and second distal end 132 are chamfered or bevelled.

The material used to constructed endovascular sleeve 10 is not particularly restricted provided of course that it: (i) sufficient integrity to by navigated through tortuous body passageways, and (ii) is non-toxic to the subject in which endovascular sleeve 10 is being navigated. Non-limiting examples of suitable materials include bioplastic polymers, a flexible metal tube and the like.

With reference to Figures 3-7, the use of endovascular sleeve 10 used to deliver a pair of guidewires will be discussed.

As shown, a bifurcated body passageway 50 comprises a proximal passageway 52 and a pair of distal passageways 54,56. The junction of distal passageways 54,56 defines a crotch 58. For clarity, the stenosis of bifurcated body passageway 50 is not illustrated.

With reference to Figure 3, a first guidewire 60 is navigated through proximal passageway 52 and into distal passageway 54 in the direction of arrow A.

With reference to Figure 4, first tubular passageway 20 is fed over guidewire 60 in the direction of arrow A and navigated until it enters distal passageway 54 and junction 40 of endovascular sleeve 10 abuts crotch 58 of bifurcated body passageway 50. In the illustrated embodiment, endovascular sleeve 10 is provided with a radioopaque marker (e.g., made of gold and the like) near or at junction 40 so that the position of junction 40 relative to crotch 58 can be monitored using conventional image radiography techniques. Once endovascular sleeve 10 is positioned in this fashion, second distal end 32 of second tubular passageway 30 opens into distal passageway 56.

With reference to Figure 5, once endovascular sleeve 10 is in place (i.e., as shown in Figure 4), a second guidewire 62 is fed through second tubular passageway 30 into distal passageway 56 in the direction of arrow A.

With reference to Figure 6, once guidewires 60,62 are positioned correctly, endovascular sleeve 10 is withdrawn from bifurcated body passageway 50 in the direction of arrow B. As will be apparent to those of skill in the art, care should be taken to avoid twisting of endovascular sleeve 10 since this could result in conveyance of the twist to guidewires 60,62.

With reference to Figure 7, once endovascular sleeve 10 is completely withdrawn from bifurcated body passageway 50, guidewires 60,62 remain with the distal ends thereof in distal passageways 54,56, respectively.

With reference to Figures 8-12, there are illustrated perspective views of the use of endovascular sleeve 10 to deliver a pair of guidewires as described hereinabove with respect to Figures 3-7.

As illustrated, endovascular sleeve 10 is introduced to a subject 70 via a suitable incision near the groin of subject 70. Generally speaking, the concordance of the perspectives view illustrated in Figures 8-12 to the enlarged view illustrated in Figures 3-7 is as follows:

Figure 8 concords with Figure 3;
Figures 9 and 10 concord with Figure 4;
Figure 11 concords with Figure 5; and
Figure 12 concords with Figures 6 and 7.

As discussed above, endovascular sleeve 10 may be regarded as an "over-the-wire/monorail" delivery system. By this it is meant that, once the sleeve is in the correct position, one tubular passageway (30) remains over a guidewire (62) such that the proximal end thereof (34) emanates from the subject whereas the proximal end (24) of the other tubular passageway (20) does not emanate from the subject. In other words, the section of the other tubular passageway (20) between the bifurcated body passageway (50) and incision (72) in the subject (70) does not completely cover the other guidewire (60).

As discussed above, endovascular sleeve 100 may be regarded as a "double over-the-wire" delivery system. By this is meant that, once the sleeve is in the correct position, both tubular passage ways (120,130) remain over their respective guidewires (60,62) such that the proximal end (24) of each tubular passageway (120,130) emanates from the subject. In other words, both guidewires (60,62) are substantially completely covered by endovascular sleeve 100.

With reference to Figure 7, once the endovascular sleeve is removed, guidewires 60,62 remain as illustrated and are substantially untwisted to the point at which they emanate from the subject. With reference to Figure 13, at this point, a catheter 80 is used to deliver a bifurcated stent to bifurcated body passageway 50. Specifically, catheter 80 comprises a balloon 82 having a pair of tubes 84,86 emanating from one end thereof. Mounted on balloon 82 is a bifurcated stent 88. Tubes 84,86 are of a conventional, annular design such that they can be disposed over their respective guidewires and can receive a fluid which is used to fill balloon 82 resulting in expansion thereof. Thus, catheter 80 is navigated over guidewires 60,62 until the bifurcated stent is in the correct position - see Figure 14. At this point, a pressurized fluid (e.g., saline) is introduced into balloon 82 via tubes 84,86 resulting in expansion of balloon 82 and stent 88 - see Figure 15. Thereafter, balloon 82 is deflated conventionally and withdrawn from bifurcated body passage way 50 leaving stent 88 in a deployed state - see Figure 16. While balloon 82 is shown as a pair of adjacent single balloons, those of skill in the art will appreciate that a bifurcated balloon could be used in place of a pair of single balloons.

While this invention has been described with reference to illustrative embodiments, this description is not intended to be construed in a limiting sense. Various modifications of the illustrative embodiments, as well as other embodiments of the invention , will be apparent to persons skilled in the art upon reference to this description. It is therefore contemplated that the appended claims will cover any such modifications or embodiments.

What is claimed is:

1. An endovascular sleeve for delivering a pair of guidewires to a bifurcated body passageway, the sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end extending beyond the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway;

characterized in that a guidewire is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire.

2. The endovascular sleeve defined in claim 1, further comprising a radioopaque marker disposed thereon.

3. The endovascular sleeve defined in claim 2, wherein the radioopaque marker is disposed at the junction.

4. The endovascular sleeve defined in any one of claims 1-3, wherein the first passageway has a substantially circular cross-section.

5. The endovascular sleeve defined in any one of claims 1-3, wherein the second passageway has a substantially circular cross-section.

6. The endovascular sleeve defined in any one of claims 1-3, wherein both the first passageway and the second passageway have a substantially circular cross-section.

7. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end extends beyond the second distal end by a margin of at least about 0.3 cm.

8. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end extends beyond the second distal end by a margin in the range of from about 0.3 to about 3 cm.

9. The endovascular sleeve defined in any one of claims 1-6, wherein the first distal end extends beyond the second distal end by a margin in the range of from about 0.5 to about 2 cm.

10. The endovascular sleeve defined in any one of claims 1-9, wherein the first distal end is chamfered.

11. The endovascular sleeve defined in any one of claims 1-9, wherein the second distal end is chamfered.

12. The endovascular sleeve defined in any one of claims 1-9, wherein both the first distal end and the second distal end are chamfered.

13. An expansible prosthesis delivery system for delivery of an expansible prosthesis to a bifurcated body passageway, the system comprising:

a catheter;

a guidewire; and

an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end extending beyond the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway;

characterized in that the guidewire is disposed in the first tubular passageway and the second tubular passageway is free of any guidewire.

14. The system defined in claim 13, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

15. The system defined in claim 14, wherein the radioopaque marker is disposed at the junction.

16. The system defined in any one of claims 13-15, wherein the first passageway has a substantially circular cross-section.

17. The system defined in any one of claims 13-15, wherein the second passageway has a substantially circular cross-section.

18. The system defined in any one of claims 13-15, wherein both the first passageway and the second passageway have a substantially circular cross-section.

19. The system defined in any one of claims 13-18, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

20. The system defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

21. The system defined in any one of claims 13-18, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

22. The system defined in any one of claims 13-21, wherein the first distal end is chamfered.

23. The system defined in any one of claims 13-21, wherein the second distal end is chamfered.

24. The system defined in any one of claims 13-21, wherein both the first distal end and the second distal end are chamfered.

25. The system defined in any one of claims 13-24, wherein the catheter comprises at least one expandable member.

26. The system defined in claim 25, wherein the expandable member is disposed adjacent a distal end of the catheter.

27. The system defined in any one of claims 25-26, wherein the catheter comprises two expandable members.

28. The system defined in any one of claims 25-27, wherein the catheter comprises a substantially Y-shaped expandable member.

29. The system defined in any one of claims 25-28, wherein the expandable member is a balloon.

30. The system defined in any one of claims 25-29, further comprising a bifurcated stent disposed on the expandable member.

31. The system defined in claim 30, wherein the bifurcated stent is mounted on the expandable member.

32. A method for delivery of a bifurcated stent to a target bifurcated body passageway having a proximal body passageway, a first distal body passageway and a second distal body passageway using an endovascular sleeve comprising a first tubular passageway and a second tubular passageway fixed with respect to one another, the first tubular passageway comprising a first distal end and a first proximal end, the second tubular passageway comprising a second distal end and a second proximal end, the first distal end being longer than the second distal end to define a junction which abuts against a crotch in the bifurcated body passageway, the method comprising the steps of:

(i) navigating a first guidewire through the primary proximal body passageway and into the first distal body passageway;

(ii) feeding the first tubular passageway of the endovascular sleeve over the first guidewire;

(iii) navigating the endovascular sleeve through the primary proximal body passageway until the first distal end is disposed in the first distal body passageway and the junction abuts a crotch in the bifurcated body passageway;

(iv) navigating a second guidewire through the second tubular passageway and into the second distal body passageway;

(v) withdrawing the endovascular sleeve from the body passageway;

(vi) guiding a catheter over the first guidewire and the second guidewire, the catheter having a bifurcated stent disposed thereon;

(vii) navigating the bifurcated stent to the target bifurcated body passageway; and

(viii) expanding the bifurcated stent.

33. The method defined in claim 32, wherein the catheter further comprises at least one expandable member on which the bifurcated stent is disposed and Step (viii) comprises expanding the expandable member to convey a radially expansive force to the bifurcated stent.

34. The method defined in claim 33, wherein the expandable member is disposed adjacent a distal end of the catheter.

35. The method defined in any one of claims 33-34, wherein the catheter comprises two expandable members.

36. The method defined in any one of claims 33-35, wherein the catheter comprises a substantially Y-shaped expandable member.

37. The method defined in any one of claims 33-36, wherein the expandable member is a balloon.

38. The method defined in any one of claims 32-37, wherein the bifurcated

stent is constructed of a plastically deformable material.

39. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of stainless steel.

40. The method defined in any one of claims 32-37, wherein the bifurcated stent is constructed of a self-expanding material.

41. The method defined in any one of claims 32-40, wherein the catheter further comprises a sheath covering the bifurcated stent and Step (viii) comprises removing the sheath to expose the bifurcated stent resulting in a radially expansive force thereon.

42. The method defined in claim 40, wherein the self-expanding material is nitinol.

43. The method defined in any one of claims 40 and 42, wherein the self-expanding material expands at a temperature of greater than about 30°C.

44. The method defined in any one of claims 40-42, wherein the self-expanding material expands at a temperature of in the range of from about 30° to about 40°C.

45. The method defined in any one of claims 32-44, wherein the endovascular sleeve further comprises a radioopaque marker disposed thereon.

46. The method defined in claim 45, wherein the radioopaque marker is disposed at the junction.

47. The method defined in any one of claims 32-46, wherein the first passageway has a substantially circular cross-section.

48. The method defined in any one of claims 32-46, wherein the second passageway has a substantially circular cross-section.

49. The method defined in any one of claims 32-46, wherein both the first passageway and the second passageway have a substantially circular cross-section.

50. The method defined in any one of claims 32-49, wherein the first distal end is at least about 0.3 cm is longer than the second distal end.

51. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.3 to about 3 cm.

52. The method defined in any one of claims 32-49, wherein the first distal end is longer than the second distal end by a margin in the range of from about 0.5 to about 2 cm.

53. The method defined in any one of claims 32-52, wherein the first distal end is chamfered.

54. The method defined in any one of claims 32-52, wherein the second distal end is chamfered.

55. The method defined in any one of claims 32-52, wherein the both the first distal end and the second distal end are chamfered.

56. The endovascular sleeve defined in any one of claims 1-12, wherein the second proximal end extends beyond the first proximal end.

57. The endovascular sleeve defined in claim 56, wherein the first tubular passageway has a length such that the first proximal end does not emanate from

a subject and the second tubular passageway has a length such that the second proximal emanates from the subject.

58. The endovascular sleeve defined in any one of claims 1-12, wherein the second proximal end the first proximal end and the second proximal end are substantially juxtaposed.

59. The endovascular sleeve defined in claim 58, wherein the first tubular passageway and the second tubular passageway have a length such that the first proximal end and the second proximal end each emanate from a subject.

60. The endovascular sleeve defined in any one of claims 1-12 and 56-59, wherein the first tubular passageway and the second tubular passageway are each constructed of a material having sufficient integrity to be navigated through tortuous body passageways.

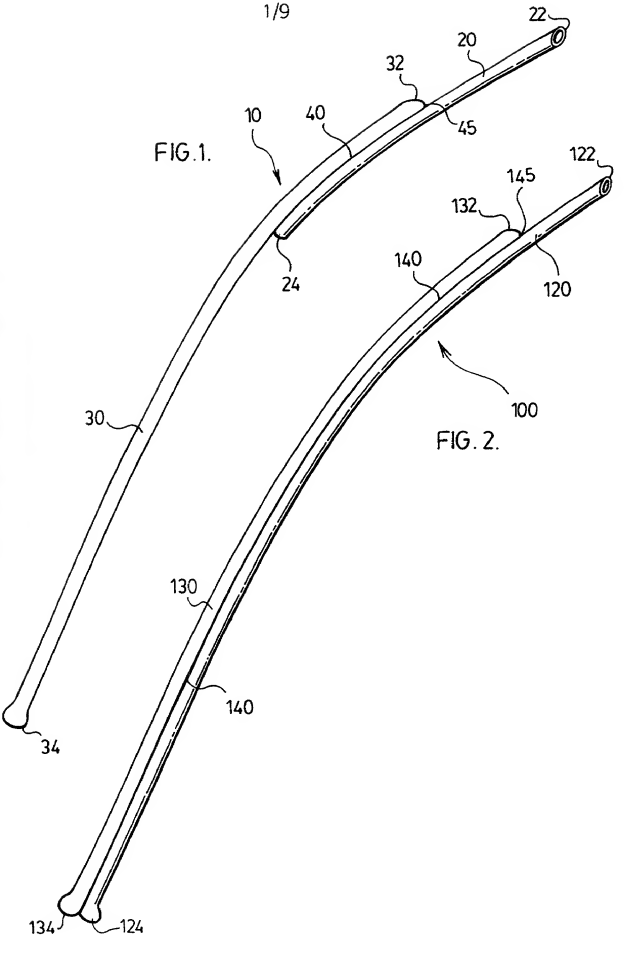


FIG. 1.

FIG. 2.

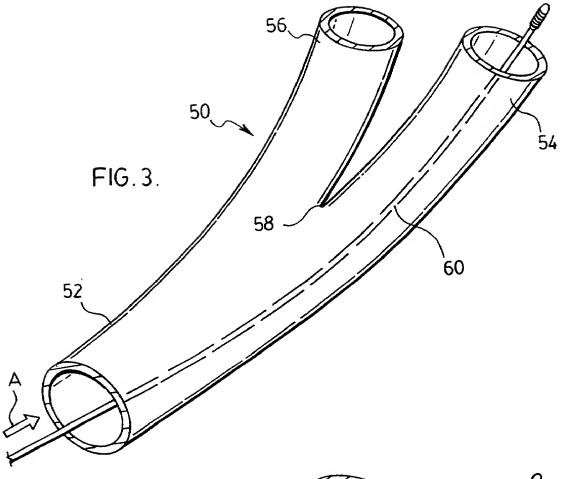


FIG. 3.

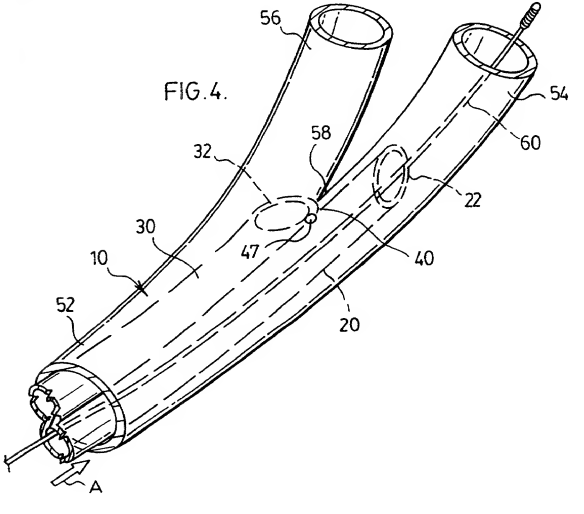
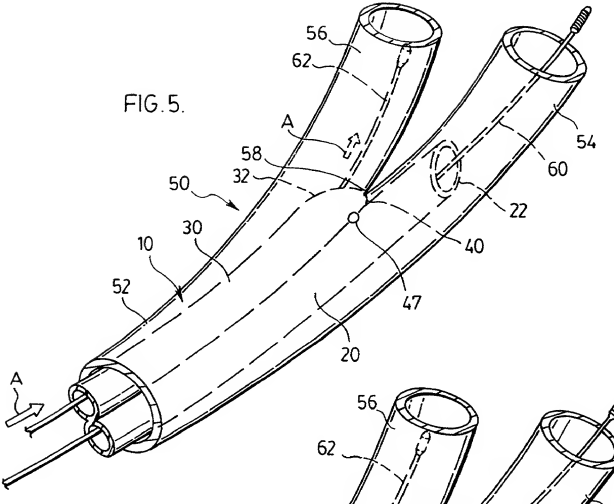


FIG. 4.

FIG.5.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62
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58
32
50
30
10
52
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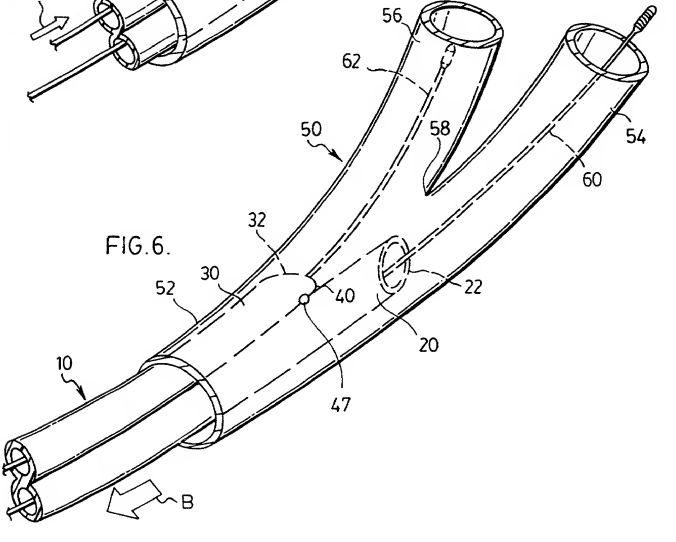
60
22
40
47
20
A

FIG.6.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10
47
B

FIG.7.

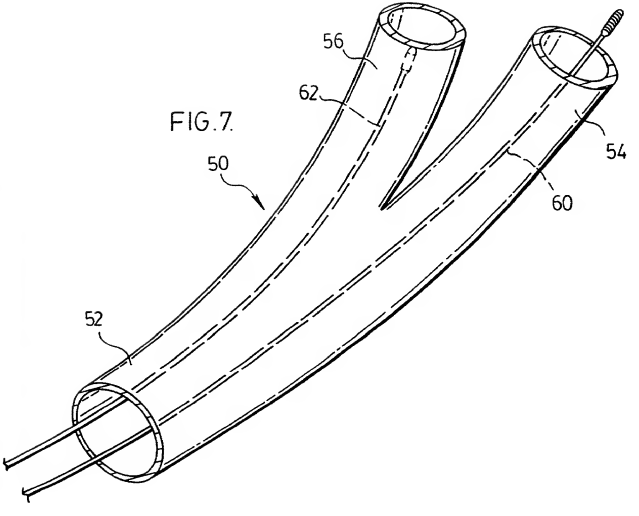


FIG.8.

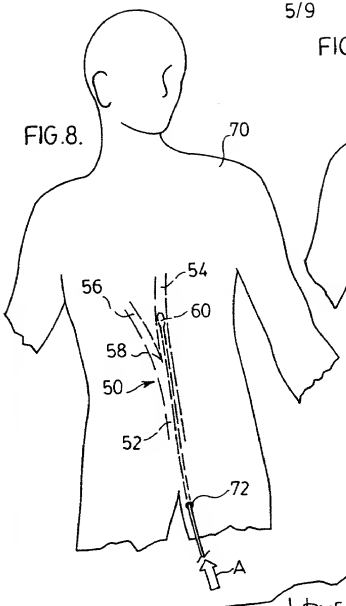


FIG.9.

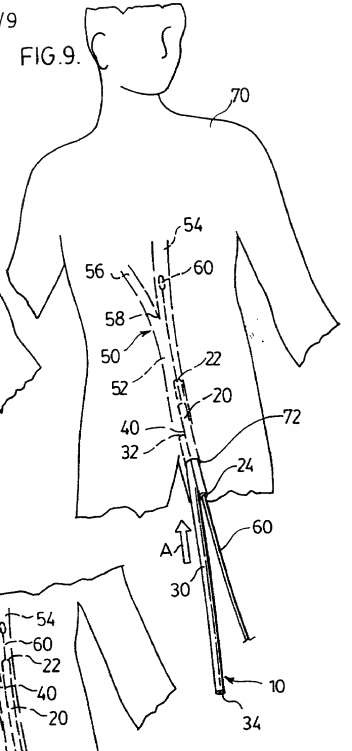


FIG.10.

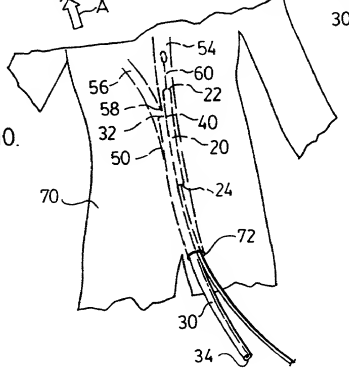


FIG. 11.

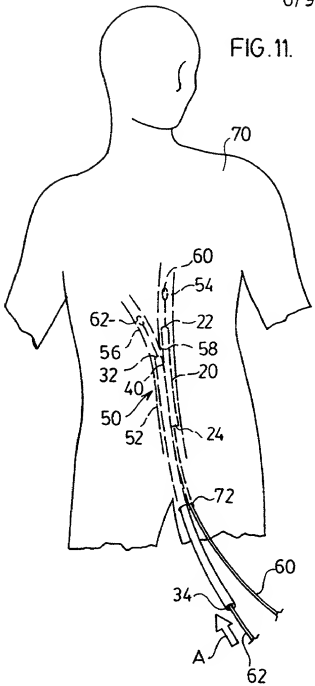
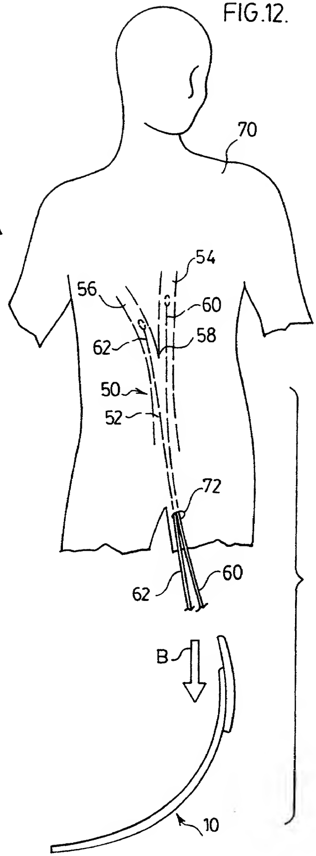


FIG. 12.



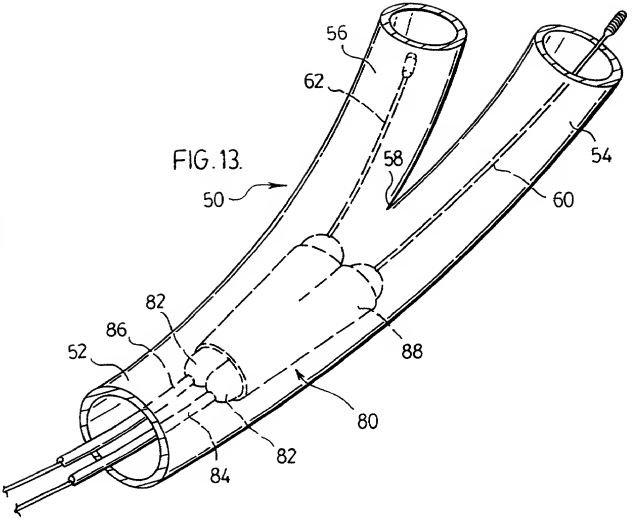


FIG. 13.

FIG. 14.

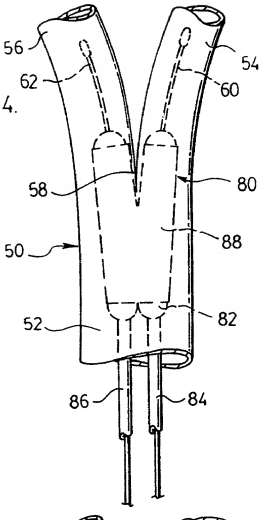


FIG. 15.

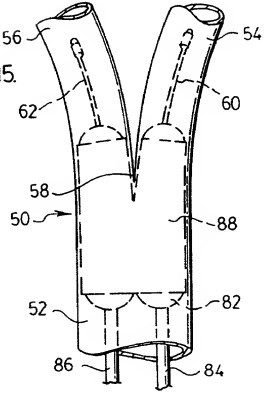
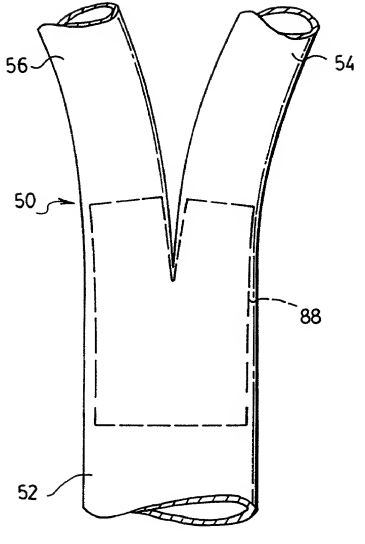


FIG.16.



COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

(Page 1)

As a below named inventor, I hereby declare that:

My residence, post office address and citizenship are as stated below next to my name;

I believe I am an original, first and joint inventor of the subject matter which is claimed and for which a patent is sought on the invention entitled BIFURCATED STENT DELIVERY SYSTEM AND METHOD OF USE the specification of which [ ] is attached hereto [X] was filed on July 20, 1999 as United States Application No. or PCT International Application No. 09/744,950and was amended on _____ (if applicable).

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b), of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designates at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed:

Country	Application No.	Filed (Day/Mo./Yr.)	(Yes/No) Priority Claimed
PCT	CA99/00695	20 July 1999	No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application No.	Filed (Day/Mo./Yr.)
60/094,950	31 July 1998

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Status

TWO DECS

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION

(Page 2)

Application No. | Filed (Day/Mo./Yr.) (Patented, Pending, Abandoned)

I hereby appoint the practitioners associated with the firm and Customer Number provided below to prosecute this application and to transact all business in the Patent and Trademark Office connected therewith, and direct that all correspondence be addressed to the address associated with that Customer Number:

KATTEN MUCHIN ZAVIS
Customer Number: 27160

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

Full Name of Sole or First Inventor Donald R. Ricci

Inventor's signature

Date 6/13/01 Citizen/Subject of Canada

Residence 4443 West 3rd Avenue, Vancouver, British Columbia, Canada CAX V6R 1M9

Post Office Address same as residence

Full Name of Second Joint Inventor, if any George A. Shukov

Second Inventor's signature

Date Citizen/Subject of United States

Residence 14440 De Bell Road, Los Altos Hills, California, U.S.A. 94022

Post Office Address same as residence

Full Name of Third Joint Inventor, if any Ian M. Parin

Third Inventor's signature

Date 6/13/01 Citizen/Subject of Canada

Residence 4511 Bellevue Drive, Vancouver, British Columbia, Canada CAX V6R 4E9

Post Office Address same as residence

(3) over

COMBINED DECLARATION AND POWER OF ATTORNEY
FOR PATENT APPLICATION
(Page 2)

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Full Name of Sole or First Inventor Donald R. Ricci
Inventor's signature _____
Date _____ Citizen/Subject of Canada
Residence 4443 West 3rd Avenue, Vancouver, British Columbia, Canada V6R 1M9
Post Office Address same as residence

Full Name of Second Joint Inventor, if any George A. Shukov
Second Inventor's signature _____
Date 6.6.01 Citizen/Subject of United States
Residence 14440 De Bell Road, Los Altos Hills, California, U.S.A. 94022
Post Office Address same as residence

Full Name of Third Joint Inventor, if any Ian M. Penn
Third Inventor's signature _____
Date _____ Citizen/Subject of Canada
Residence 4511 Bellevue Drive, Vancouver, British Columbia, Canada V6R 4E9
Post Office Address same as residence

COMBINED DECLARATION AND POWER OF ATTORNEY FOR PATENT APPLICATION
(Page 1)

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I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

I acknowledge the duty to disclose information which is material to patentability as defined in 37 CFR §1.56.

I hereby claim foreign priority benefits under 35 U.S.C. §119(a)-(d) or §365(b), of any foreign application(s) for patent or inventor's certificate, or § 365(a) of any PCT international application which designates at least one country other than the United States, listed below and have also identified below any foreign application for patent or inventor's certificate, or PCT international application having a filing date before that of the application on which priority is claimed:

Country	Application No.	Filed (Day/Mo./Yr.)	(Yes/No) Priority Claimed
PCT	CA99/00695	20 July 1999	No

I hereby claim the benefit under 35 U.S.C. § 119(e) of any United States provisional application(s) listed below:

Application No.	Filed (Day/Mo./Yr.)
60/094,950	31 July 1998

I hereby claim the benefit under 35 U.S.C. § 120 of any United States application(s), or § 365(c) of any PCT international application designating the United States, listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States or PCT international application in the manner provided by the first paragraph of 35 U.S.C. § 112, I acknowledge the duty to disclose information which is material to patentability as defined in 37 C.F.R. § 1.56 which became available between the filing date of the prior application and the national or PCT international filing date of this application.

Status

VERIFIED STATEMENT (DECLARATION) CLAIMING SMALL ENTITY STATUS (37 CFR 1.9(f) AND 1.27 (b)) - INDEPENDENT INVENTOR			Docket No. 13202.00266
Serial No. 09/744,950	Filing Date 20 July 1999	Patent No.	Issue Date

Applicant/ Patentee: **NOVO RPS ULC**

Invention: **BIFURCATED STENT DELIVERY SYSTEM AND METHOD OF USE**

As a below named inventor, I hereby declare that I qualify as an independent inventor as defined in 37 CFR 1.9(c) for purposes of paying reduced fees under section 41(a) and (b) of Title 35, United States Code, to the Patent and Trademark Office with regard to the invention entitled above and described in:

- ☐ the specification to be filed herewith.
- ☒ the application identified above.
- ☐ the patent identified above.

ave not assigned, granted, conveyed or licensed and am under no obligation under contract or law to assign, grant, nvey or license, any rights in the invention to any person who could not be classified as an independent inventor der 37 CFR 1.9(c) if that person had made the invention, or to any concern which would not qualify as a small siness concern under 37 CFR 1.9(d) or a nonprofit organization under 37 CFR 1.9(e).

ch person, concern or organization to which I have assigned, granted, conveyed, or licensed or am under an gation under contract or law to assign, grant, convey, or license any rights in the invention is listed below:

- ☒ No such person, concern or organization exists.
- ☐ Each such person, concern or organization is listed below.

*NOTE: Separate verified statements are required from each named person, concern or organization having rights to the invention averring to their status as small entities (37 CFR 1.27)

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____

☐ Individual ☐ Small Business Concern ☐ Nonprofit Organization

FULL NAME _____
ADDRESS _____

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I acknowledge the duty to file, in this application or patent, notification of any change in status resulting in loss of entitlement to small entity status prior to paying, or at the time of paying, the earliest of the issue fee or any maintenance fee due after the date on which status as a small entity is no longer appropriate. (37 CFR 1.28(b))

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application, any patent issuing thereon, or any patent to which this verified statement is directed.

NAME OF INVENTOR Donald R. Ricci
SIGNATURE OF INVENTOR _____ DATE: 6/7/01

NAME OF INVENTOR George A. Shukov
SIGNATURE OF INVENTOR _____ DATE: _____

NAME OF INVENTOR Ian M. Penn
SIGNATURE OF INVENTOR _____ DATE: 11/6/01

NAME OF INVENTOR _____
SIGNATURE OF INVENTOR _____ DATE: _____

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NAME OF INVENTOR Donald R. Ricci

SIGNATURE OF INVENTOR _____ DATE: _____

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SIGNATURE OF INVENTOR _____ DATE: 6-6-01

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